State of Wisconsin
Governor Scott Walker

**Department of Agriculture, Trade and Consumer Protection**
Ben Brancel, Secretary

**DATE:** October 18, 2013

**TO:** Board of Agriculture, Trade and Consumer Protection

**FROM:** Ben Brancel, Secretary
Steve Ingham, Administrator, Division of Food Safety

**SUBJECT: Regulation of Drug Residues in Animals for Human Food, and affecting small business; Rulemaking Scope Statement**

**PRESENTED BY:** Steve Ingham, Division of Food Safety

**REQUESTED ACTION:**

At the November 13, 2013 Board meeting, the Department of Agriculture, Trade and Consumer Protection (DATCP) will ask the DATCP Board to approve a "scope statement" (copy attached) for potential changes to current DATCP rules related to meat and meat food products. If adopted, the changes will specify corrective actions to be enforced against livestock producers who, on two or more occasions during any calendar year, submit animals which test positive for any drug residue to be slaughtered at a state- or federally-inspected meat establishment for human consumption.

Medications are important for maintaining healthy livestock but, if not carefully managed, drug residues may remain in animals submitted for slaughter. These residues can threaten the health of people who consume the meat. The US Department of Agriculture requires meat establishment operators to check the published Residue Repeat Violators list, which identifies producers whose animals have had two or more positive drug residue test results in the past year. If the operator accepts animals from producers on the list, regulatory action is taken against the establishment operator. Producers responsible for submitting animals with drug-residues for slaughter face no corrective action by the state.

The department proposes consulting with industry to determine whether to implement mandatory education-based corrective action, involving the livestock producer and his/her veterinarian, to be enforced the first time a producer is determined to be a repeat residue violator. Although the frequency of such a corrective action is expected to be very low, a corrective action may be an important tool in ensuring that the safety of Wisconsin meat and meat food products is maintained.

A scope statement spells out the general purpose and scope of a proposed rule. DATCP may not begin drafting a proposed rule (including a proposal to amend or repeal an existing rule) until the Governor approves a scope statement for that rule as required under s. 227.135(2), Stats. This scope statement was approved by the Governor on October 11, 2013. Wisconsin statutes also require the DATCP Board to approve a scope statement before the department can begin to draft a proposed rule. DATCP is required to publish a draft scope statement

in the Wisconsin Administrative Register, and file a copy with the Department of Administration (DOA), at least 10 days before the Board approves the scope statement. DATCP filed the attached scope statement with the Legislative Reference Bureau for publication in the October 31, 2013 issue of the Wisconsin Administrative Register and filed a copy with DOA as required.

# STATEMENT OF SCOPE

## Department of Agriculture, Trade and Consumer Protection (DATCP)

**Rule No.:** Ch. ATCP 55, Wis. Adm. Code

**Relating to:** Drug residues in animals for human food, and affecting small business.

**1. Description of the objective of the rule:**

The department proposes a rule revision for ch. ATCP 55, Wis. Adm. Code, specifying corrective actions to be enforced against livestock producers registered under Wisconsin's livestock premises regulations who, on two or more occasions during any calendar year, submit animals, which test positive for any drug residue, to be slaughtered at a state- or federally-inspected meat establishment for human consumption.

**2. Description of existing policies relevant to the rule and of new policies proposed to be included in the rule and an analysis of policy alternatives; the history, background and justification for the proposed rule:**

Medications are important for maintaining healthy livestock. However, if not carefully managed, drug residues may remain in animals submitted for slaughter. Residues of medications, particularly antibiotics and anti-inflammatory agents, in meat can pose a direct health risk to people who consume the meat. For example, some people may have an allergic reaction if exposed to penicillin. The drug flunixin may cause gastrointestinal and kidney problems. Drug residues may disrupt normal meat fermentation processes, such as is needed to make summer sausage, and increase the risk that disease-causing bacteria will grow during processing.

Meat establishment operators are expected by the United States Department of Agriculture - Food Safety and Inspection Service (USDA-FSIS) to check the published Residue Repeat Violators list. The list identifies livestock producers whose animals have had two or more positive drug residue test results in the past year. Meat establishment operators are also expected to take appropriate measures before accepting animals from these producers. Regulatory action, if it is taken by USDA, is taken against the establishment operator. However, there is no state regulatory corrective action that can be enforced against these repeat offenders. Recent federal data suggest that dairy cattle are responsible for a high proportion of repeat tissue drug residue offenses. As a leading producer of dairy cattle, the reputation of Wisconsin's agriculture is jeopardized by Wisconsin producers who repeatedly violate prohibitions against drug residue in livestock and meat products.

Currently ATCP 55 (Meat and meat food products) addresses the production of meat and meat food products starting with the submission of an animal for slaughter for human consumption and, by reference, adopts United States Department of Agriculture regulations prohibiting the slaughter of "downer" cattle (non-ambulatory) for human food or feed destined for bovine

animals. ATCP 57 (Inedible animal by-products) deals generally with the slaughter of animals not for human consumption and the collection and processing of inedible byproducts of animal slaughter. Chapter 12 (Animal markets, dealers and truckers) addresses the handling of downer animals and requires that these animals be slaughtered for rendering or euthanized.

The department proposes consulting with industry to determine whether to implement mandatory education-based corrective action, involving the livestock producer and his/her veterinarian, to be enforced the first time a producer is determined to be a repeat residue violator. The department also proposes consideration of more stringent corrective actions, which would be determined after consultation with industry, to be enforced following violations that occur after the initial corrective action is completed.

Policy Alternatives. If the department does not alter the current rules, the department will lack a clearly stated rapid enforcement step for tissue drug-residue repeat violations. Federal action against residue repeat violators is generally not taken unless the US Food and Drug Administration investigates, issues a warning letter and, upon further violations, obtains an injunction against the livestock producer. Warning letters and injunctions are seldom issued by the FDA on the basis of tissue drug-residue repeat violations. Instances of tissue drug-residue repeat violation could reduce consumer confidence in the safety of Wisconsin's meat products and place the reputation of Wisconsin's livestock industry in jeopardy.

**3. Statutory authority for the rule (including the statutory citation and language):** Statutory Authority: ss. 93.07 (1), 97.09 (4), 97.42 (4), 95.38 and 95.67, Stats.

**93.07 Department duties.** It shall be the duty of the department:

**(1)** REGULATIONS. To make and enforce such regulations, not inconsistent with law, as it may deem necessary for the exercise and discharge of all the powers and duties of the department, and to adopt such measures and make such regulations as are necessary and proper for the enforcement by the state of chs. 93 to 100, Stats., which regulations shall have the force of law.

**97.09 Rules.**

**(4)** The department may, by rule, establish and enforce standards governing the production, processing, packaging, labeling, transportation, storage, handling, display, sale, including retail sale, and distribution of foods that are needed to protect the public from the sale of adulterated or misbranded foods.

**97.42 Compulsory inspection of animals, poultry and carcasses.**

**(4)** RULES. The department may issue reasonable rules requiring or prescribing any of the following:

(a) The inspection before and after slaughter of all animals and poultry killed or dressed for human consumption at any establishment.

**95.38 Altering records; tampering with ear tags.**

(1) It shall be unlawful for any person to in any manner change any test record, falsely record any test, misrepresent the identification of any animal or any other material fact on any test record, certificate of veterinary inspection, vaccination record, claim for indemnity, or any disease control report or application to the department. It shall be unlawful for any person to induce or to conspire with another, either directly or indirectly, to do any of the said prohibited acts.

(2) No person is permitted to in any way tamper with, insert or remove from the ear of any animal any ear tag or registration mark which is or may be used for identification in disease control work except upon authorization from the department.

(3) The department may adopt rules that are necessary to administer this section.

**95.67 Proper use of animal care and disease control products.** No person may use chemical, biological or disease control products in the treatment or care of food producing animals without substantially complying with instructions, warnings and directions for use on the product label. No animal or food product including milk of the animal shall be marketed for processing or use as food prior to the time specified on the label of a product used in the treatment or care of the animal. This section applies neither to licensed veterinarians who prescribe or administer drugs in conformity with federal restrictions nor to persons using drugs in a manner prescribed by a licensed veterinarian. This section shall not prevent a farmer from administering animal disease control products to livestock in compliance with instructions on the product label.

**4. Estimate of the amount of time that state employees will spend to develop the rule and of other resources necessary to develop the rule:**

DATCP estimates that it will use approximately 0.10 FTE staff to develop this rule. That includes time required for investigation and analysis, rule drafting, preparing related documents, coordinating stakeholder meetings, holding public hearings and otherwise communicating with affected persons and groups. DATCP will use existing staff to develop this rule.

**5. Description of all entities that may be impacted by the rule:**

Consumers, meat establishment operators, and livestock producers will all benefit from the department having progressive enforcement capabilities for repeat tissue drug-residue violations.

**6. Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule:**

Federal meat and poultry inspection regulations require meat and poultry processors to adopt Hazard Analysis and Critical Control Point (HACCP) systems. HACCP is an approach for preventing food safety hazards that involves identifying key food processing steps essential for ensuring safety. Plants must develop a plan to monitor and document that each of these key steps is functioning properly and minimizing food safety risks. As part of their HACCP plan, federally-inspected plants are required by 9 CFR 417.2 (a) (3) (v) to identify preventive measures for food safety hazards that could arise from drug residues. Drug residues include veterinary drugs, pesticides, and environmental contaminants.

One approach for minimizing drug residue risks is for producers to avoid purchasing animals from sources that have had drug residue violations in the past. Since past performance is often

the best indicator as to whether an animal may have a drug residue problem, federal plants are expected to consult the federal Residue Repeat Violator List before purchasing animals for slaughter. The National Residue Program (NRP) at FSIS has collected data on drug residues in meat, poultry and egg products since 1967. Producers who are found to have had more than one residue violation in the previous 12 months under this sampling program are placed on the federal Residue Repeat Violator List.

State meat inspection programs operate under a cooperative agreement with the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS). Under this agreement, state meat inspection programs are required to adopt regulations that are "at least equal to" federal meat and poultry inspection regulations. In addition, Wisconsin is one of three states recently accepted into the Cooperative Interstate Shipment (CIS) program allowing certain selected meat establishments to ship their products in interstate commerce. States in the CIS program must adopt regulations that are the "same as" federal meat inspection regulations.

The proposed rule will ensure Wisconsin's state meat inspection program is consistent with federal regulations and expectations for minimizing the risk of drug residue violations at state-inspected meat plants. It will enhance the effectiveness of these procedures by adding an additional educational corrective action that would be implemented well before federal regulatory action is needed.

**7. Anticipated economic impact**

This rule change is anticipated to have no impact on the vast majority of livestock producers who follow existing regulations and have a strong working relationship with their veterinarian. There will be a minor short-term negative economic impact on livestock producers who must attend a workshop and improve documentation of animal medications as a result of the proposed rule. To the extent that the proposed rule prevents drug residue problems and condemnation of carcasses, there will be a positive long-term economic impact. The rule will not modify fees or have an economic impact on local governmental units or public utility taxpayers.

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9-23-13
Date Submitted